APPENDIX E: CONFIDENTIAL BUSINESS INFORMATION

Companies must provide an explanation for claiming certain information in a MCAN or exemption submission to be Confidential Business Information (CBI), and they may need to negotiate with the Agency to resolve disputes concerning these claims. In addition, such substantiation will be required in connection with requests made with TERA submissions, upon Agency request. The costs in this appendix are calculated from a zero baseline without consideration of current regulatory requirements. Estimates of the costs are developed where possible, but in other cases limitations in the available data permit only qualitative estimates of costs to be made.

A. Final Rule Options for CBI Substantiation

EPA proposed "upfront" or "advance" substantiation of CBI claims made in submissions for general commercial use and has incorporated that requirement into the rule. Lack of substantiation would result in the submission being declared incomplete, resulting in a delay in the beginning of the review period.

For TERAs, substantiation would be required only if there is a specific need, such as pursuant to a Freedom of Information Act (FOIA) requesting disclosure of information claimed as confidential. (Submitters currently are required to provide upfront substantiation for CBI claims in PMNs for microorganism releases, however).

B. Quantified Costs of CBI Substantiation

Because the Agency is uncertain as to how frequently the need to substantiate CBI claims in connection with TERA submissions will arise, quantified costs of CBI substantiation conservatively assume substantiation for all TERAs, as well as MCAN. EPA's methodology and results follow. The substantiation process can be divided into fours parts: (1) strategy development, (2) substantiation development, (3) form preparation, and (4)

review. The first part, strategy development involves determining which elements of information in the submission to claim as confidential, including categories of claims and linkages. The second stage, substantiation development involves developing responses to questions or requirements in each EPA category claimed confidential, determining the appropriate linkages, and obtaining certification of the claims by corporate management. The third stage, form preparation, involves preparing sanitized attachments, and making annotations on the complete MCAN to indicate confidentiality assertions. The fourth parts, review, involves reviewing the completed submission and "sanitized" attachments with in-house staff.

For both TERAs and MCANs, submitters would have to fully substantiate CBI claims when requested by the Agency and would be required to resolve disputes concerning claims. In each case, certain costs associated with confidentiality would be incurred at the time of submission. Costs associated with strategy development, form preparation, and review would be incurred at the time of the submission by all firms with CBI claims. The costs associated with these parts are included in the costs of submission developed in Appendix D.

As mentioned above, this analysis assumes CBI substantiation costs will be incurred for all TERAs. However, the timing of the substantiation may affect the magnitude of such costs. For upfront substantiation, the substantiation developments cost would be imposed on all firms claiming information to be confidential at the time of submission. For TERAs, where substantiation is only required after an FOIA request, only those firms whose submissions were subject to these requests following submission would face these costs. Historically, most FOIA requests follow within sixty days of submission under the New Chemicals Program so the delay in these costs is not significant enough to warrant discounting these costs. For this reason, and

because the Agency expects a large proportion of submissions for microorganisms with environmental applications to result in FOIA requests, costs estimated based on an assumption of upfront substantiation are believed to provide a reasonable representation of actual costs incurred under the rule.

The average cost of an initial CBI substantiation is estimated at between $1,015 and $2,852 for a first-time microbial submission, as shown in Table E-1*. Subsequent substantiations by the same company are likely to be much less expensive, since companies may reuse material prepared for previous CBI substantiations (e.g., see PMNs P88-1115 through P88-1122). Individual substantiation costs could be higher or lower than estimated here, depending on the amount and types of information claimed confidential.

The TERA cost shown in Table E-1 is lower than the MCAN cost because there are fewer substantiation questions for R&D releases than for non-R&D releases. The "low" costs (see Table E-2) assume that initial substantiation answers tend to be general and less detailed. The "high" costs (see Table E-3) assume that some answers are more detailed and more tailored to the CBI item claimed (see BTI 1988).

The follow-on submission costs (see Tables E-4 and E-5), i.e., costs of substantiations for subsequent or "follow-on" TERAs and MCANs for similar products, assume previous substantiations are reused to the extent feasible. However, even for follow-on submissions, the company would need to verify that the answers have not changed. In addition, some statement may need to be modified or changed. The follow-on costs for a MCAN presented in Table E-1

In other analyses, EPA has estimated CBI substantiation costs for chemical PMNs at $1755 (ICF 1983) and CBI substantiation costs for reporting under the Comprehensive Assessment Information Rule (CAIR) at $807 (Kearney-Centaur 1989). The Chemical Manufacturers Association estimated CBI substantiation costs at about $300 per report, based on survey responses from eight plants (CMA 1989).

Table E-1. CBI Upfront Substantiation Costs

	First time submission	Follow-on Submission
TERA	$1,015 - $1,509	$560 - $641
MCAN	$1,559 - $2,852	$1,104 - $1,984[a]

[a] MCAN follow-on cost assumes that the MCAN follows a TERA.

Source: ETD estimates, Tables E-2, E-3, E-4, and E-5.

Table E 2 Estimated Cost of First-Time Up-Front CBI Substantiation (Low Cost)

Substantiation Question # or Task	Clerical $25.00	Jr Prof $54.14	Sr Prof $71.35	Res Mgr $103.99	Attny $103.99	$ Cost
TERAs:						
Establish items to be claimed CBI		0.5		1		$131
Existence of past patents (d1)		0.5			0.5	$79
Availability to competetitor and ability to reverse engineer (d2)		2	1			$180
Harm from ID disclosure (d3)		0.5	0.5		0.5	$115
Microbe ID/health & safety (e1)		1	1			$125
CBI in health & safety study (e2)			0.5			$36
Mgt/legal oversight, misc. clerical	1.5			1	2	$349
Total for R&D submissions	1.5	4.5	3	2	5	$1,015
MCANs/Tier II Exemptions:						
Answer questions listed for TERA (above)	1.5	4.5	3	2	3	$1,015
Period of confidentiality (c1)			0.5			$36
Company procedures for protection of CBI (c2)	0.5	0.5				$40
Previous outside disclosure (c3,4)		1	0.5			$90
Other federal determinations on CBI (c5)		0.5				$27
Competitive harm, market entry resulting from disclosure (c6 7)		2	0.5			$144
Additional Legal Review					2	$208
Total for non-R&D	2	8.5	4.5	2	5	$1,559

Notes:

Assumes no previous microbial submission substantiations provided to EPA.

Numbers in parentheses ( ) refer to Final Rule paragraph 725.94.

Labor rates are from Kearney-Centaur estimates of fully-loaded rates (Kearney-Centaur 1988)

Source: EPA estimates

Table E-3 Estimated Cost of First-Time Up-Front CBI Substantiation (High Cost)

Substantiation Question # or Task	Hours (Fully Loaded Hourly Rate)					
	Clerical	Jr Prof	Sr Prof	Res Mgr	Attny	$ Cost
	$25.00	$54.14	$71.35	$103.99	$103.99	
TERAs:						
Establish items to be claimed CBI		2		1		$212
Existence of past patents (d1)		0.5			0.5	$79
Availability to competetitor and ability to reverse engineer (d2)		3	1.5			$269
Harm from ID disclosure (d3)		1	0.5		0.5	$142
Microbe ID/health & safety (e1)		2	2			$251
CBI in health & safety study (e2)		1	0.5			$90
Mgt/legal oversight, misc. clerical	2			2	2	$466
Total for R&D submissions	2	9.5	4.5	3	3	$1,509
MCANs/Tier II Exemptions						
Answer questions l sted for TERA (above)	2	9.5	4.5	3	3	$1,509
Period of confidentiality (c1)		0.5	0.5			$63
Company procedures for protection of CBI (c2)	1	1				$79
Previous outside disclosure (c3,4)		2	0.5			$144
Other federal determinations on CBI (c5)		1				$54
Competitive harm, market entry resulting from disclosure c6,7)		7		2		$587
Additional Legal Review					4	$416
Total for non-R&D	3	21	5.5	5	7	$2,852

Notes:

Assumes no previous microbial submission substantiations provided to EPA.

Numbers in parentheses refer to Final Rule paragraph 725.94.

Source EPA estimates

Table E-4 Estimated Cost of Follow-on Up-Front CBI Substantiation (Low Cost)

Substantiation Question # or Task	Clerical	Jr Prof	Sr Prof	Res Mgr	Attny	$ Cost
	$25.00	$54.14	$71.35	$103.99	$103.99	
TERAs:						
Establish items to be claimed CBI		0.5		1		$131
Existence of past patents (d1)		0.5			0.5	$79
Availability to competetitor and ability to reverse engineer (d2)						$0
Harm from ªD disclosure (d3)						$0
Microbe ID/health & safety (e1)						$0
CBI in health & safety study (e2)						$0
Mgt/legal oversight, misc clerical	1.5			1	2	$349
Total for R&D submissions	1.5	1	0	2	2.5	$560
MCANs/Tier II Exemptions:						
Answer questions listed for TERA (above)	1.5	1	0	2	2.5	$560
Period of confidentiality (c1)						$0
Company procedures for protection of CBI (c2)						$0
Previous outside disclosure (c3,4)		1	0.5			$90
Other federal determinations on CBI (c5)		0.5				$27
Competitive harm, market entry resulting from disclosure =6 7)						$0
Additional Legal Review					1	$104
Total for non-R&D	1.5	2.5	0.5	2	3.5	$780

Notes:

Assumes company has made previous similar submission

Numbers in parentheses ( ) refer to Final Rule paragraph 725.94.

Labor rates are from Kearney-Centaur estimates of fully-loaded rates (Kearney-Centaur 1988

Source EPA estimates

Table E 5 Estimated Cost of Follow-on Up-Front CBI Substantiation (High Cost)

Substantiation Question # or Task	Clerical	Jr Prof	Sr Prof	Res Mgr	Attny	$ Cost
	$25.00	$54.14	$71.35	$103.99	$103.99	
TERAs:						
Establish items to be claimed CBI		2		1		$212
Existence of past patents (d1)		0.5			0.5	$79
Availability to competetitor and abil ty to reverse engineer (d2)						$0
Harm from ID disclosure (d3)						$0
Microbe ID/health & safety (e1)						$0
CBI in health & safety study (e2)						$0
Mgt/legal oversight, misc clerical	1 5			1	2	$349
Total for R&D submissions	1 5	2.5	0	2	2.5	$641
MCANs/Tier I Exemption Submissions·						
Answer questions listed for TERA (above)	1 5	2.5	0	2	2.5	$641
Period of confidentiality (c1)						$0
Company procedures for protection of CBI (c2)						$0
Previous outside disclosure (c3,4)		1	0.5			$90
Other federal determinations on CBI (c5)		0.5				$27
Competitive harm, market entry resulting from disclosure (c6,7)						$0
Additional Legal Review					2	$208
Total for non-R&D	1.5	4	0.5	2	4.5	$966

Notes:

Assumes company has made previous similar submission

Numbers in parentheses refer to Final Rule paragraph 725.94

Labor rates are from Kearney-Centaur estimates of fully-loaded rates (Kearney-Centaur 1988)

Source: EPA estimates

assume that the portions required for a TERA are repeated from previous submissions but the questions required only on MCAN are prepared for the first time.

C. Unquantified Costs of CBI Substantiation

Submitters also may need to resolve disputes with EPA over confidentiality claims, a process that can take months. These negotiation costs are not quantified in the RIA, however, they may be incurred regardless of whether upfront substantiation is required.

Industry commenters have suggested that reporting requirements under TSCA could result in commercially sensitive information becoming public, with possible harm to patent rights and innovation.* These effects were not analyzed for this RIA and it is not known whether they would be significant. An upfront CBI substantiation requirement is unlikely, however, to interfere with patent or trade secret rights or innovation. This is because failure to provide initial substantiation would result in return of the submission, not release of information.

D. Detailed Method

ETD estimated CBI costs by comparing CBI substantiation questions with substantiations from BioTechnica International (BTI) related to past PMNs (BTI 1987, BTI 1988). The estimates were prepared by an EPA economist and reviewed by an EPA attorney, both of them familiar with microbial notifications. The BTI submissions were used because at the time this section was drafted, they were the only substantiations EPA had received for microorganisms for environmental application and were the only substantiations available in the public docket for microbial submissions.

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* See for example public comments in EPA Docket #OPTS-00049c by the Chemical Manufacturers Association and the Industrial Biotechnology Association.

The costs of the BTI substantiations themselves were not estimated since the questions answered by BTI were somewhat different from the questions in the rule. Rather, the BTI substantiations were used as a guide to the depth of information likely to be submitted to and accepted by EPA as constituting an upfront substantiation for the purposes of starting the review clock.

To obtain the cost estimates, EPA estimated the type of expertise, tasks, and hours needed to answer each question, and applied the standard fully-loaded wage rates that have been used in other parts of this Regulatory Impact Analysis (Kearney-Centaur 1988; see Chapter IV). In addition, an attorney was assumed to cost the same as a Research Manager ($103.99/hour).

There is considerable uncertainty concerning these estimates. Some of the uncertainties cannot be resolved at this point because they depend on the nature of items actually claimed as CBI and future EPA policies concerning the depth of information acceptable as an "upfront substantiation." Other uncertainties might be resolved through further research. However, due to the relatively low cost of upfront CBI substantiations, EPA felt that its resources would be better directed toward analyzing more critical components of rule costs.

E. Other Assumptions

In estimating costs, it was assumed that EPA would accept fairly general answers to questions for the upfront substantiation. This assumption is based on the observation that the BTI October 5, 1987 answers to EPA substantiation questions were fairly general; most could apply to all CBI items and could be reused from submission to submission. (BTI's May 12, 1988 answers were more tailored to particular CBI claims.) The BTI answers seemed to be based on knowledge which senior people would already know or which would be readily available from company files.

An important assumption was that submitters could anticipate the depth

of information and nature of answers which EPA would accept. If submitters believed, perhaps erroneously, that EPA would demand comprehensive and detailed substantiations in order to declare a submission complete, they might spend more effort to supply detailed answers.

It was also assumed that a submitter would make enough CBI claims to trigger each question. In actuality, some questions may not require answers because the submitter has not made a claim triggering that question.